K033628

JAN 16 2004

Summary of Safety and effectiveness

Submitter:

Company Name: Heraeus Kulzer, Inc.

Address: 4315 South Lafayette Blvd.
South Bend, Indiana 46614

Telephone No.: 574-299-6662

Fax No.: 574-299-6616

Date: November 17, 2003

Name of Device

Classification Name: Preformed Plastic Denture Tooth

Proprietary Name: Artic®

Common Name: Denture Tooth

Equivalent Device

JelDent Basic [K000213]
Premium [K011130]

Description for the Premarket Notification

Artic is classified as Preformed Plastic Teeth (21C.F.R. § 872.3590)

Under this submission the intended use is the same and is equivalent to Heraeus Kulzer's already 510(K)-cleared JelDent Basic® [K000213] and Premium [K011130].

Artic artificial resin teeth are compatible with all denture base resins. If necessary special instructions for the bonding to denture base resins are included in the users instruction of the denture base.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 6 2004

Ms. Cheryl V. Zimmerman
Director, Quality Operations & Regulatory Affairs
Heraeus Kulzer, Incorporated
4315 South Lafayette Boulevard
South Bend, Indiana 46614-2517

Re: K033628
Trade/Device Name: Artic®
Regulation Number: 872.3590
Regulation Name: Performed Plastic Denture Tooth
Regulatory Class: Class II
Product Code: ELM
Dated: November 17, 2003
Received: November 24, 2003

Dear Ms. Zimmerman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

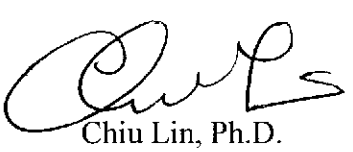
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033628

510(k) Number (if Known): _____

Device Name: Artic

Indications For Use:

Artic line are artificial synthethic resin permanent teeth. The enamel and dentine layers of HK teerh are highly cross-linked and suit the rate of natural abrasion. The base of the tooth is less cross-linked to achieve optimum bonding between the tooth and the denture acrylic

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033628